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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,794	07/12/2001	Jan Simon	24741-1505	3688

26633 7590 07/30/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,794

Applicant(s)

SIMON ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,36-43,57 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 and 57 is/are rejected.
- 7) ☒ Claim(s) 36-43 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/763,794.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 5/12/2003 (paper no. 15) is acknowledged and entered into the record. Accordingly, claims 35,44-56, and 59 are canceled without prejudice or disclaimer. Claim 60 is newly added.
2. Claims 34, 36-43, 57, and 60 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claim 57 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant's arguments or amendments to the claims have overcome the rejections of claims 34-43 as it reads on the size of the hyaluronic acid building blocks. However, the rejection of claim 57 as it pertains to vaccines is maintained, because applicant has not addressed the issue of a vaccine made by the instantly claimed process.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claim 34 under 35 USC 102(b) as being anticipated by Wenge *et al* is maintained for the reasons of record. Applicant argues that Wenge *et al* teaches a process of maturation using the high molecular weight hyaluronic acid fragments, while the newly amended claims recite a method of using low molecular weight hyaluronic acid having a size of 2000-500 Daltons. Applicant's arguments are not found persuasive because the claims as currently interpreted still read on hyaluronic acid proteins that are of larger molecular weight because of the recitation of the term "comprises". In the absence of evidence to the contrary, high molecular weight

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hyaluronic acid inherently would have at least 2-12 building blocks, given that smaller fragments have at least 2-12.

5. The rejection of claims 57 under 35 USC 102(b) as being anticipated by Noble *et al* is maintained for the reasons of record. Applicant argues that Noble *et al* teach hyaluronic acid fragments that are 200,000 daltons, while that of the instantly claimed invention are 2000-5000 Daltons. Applicant's arguments are not found persuasive because the claims as currently interpreted still read on hyaluronic acid proteins that are of larger molecular weight because of the recitation of the term "comprises". In the absence of evidence to the contrary, high molecular weight hyaluronic acid inherently would have at least 2-12 building blocks, given that smaller fragments have at least 2-12.

All rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 15.

Conclusion

6. No claim is allowed. Claims 35-43 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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~~A shortened statutory period for reply to this final action is set to expire THREE~~
MONTHS from the mailing date of this action. In the event a first reply is filed within
TWO MONTHS of the mailing date of this final action and the advisory action is not
mailed until after the end of the THREE-MONTH shortened statutory period, then the
shortened statutory period will expire on the date the advisory action is mailed, and any
~~extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of~~
the advisory action. In no event, however, will the statutory period for reply expire later
than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Christopher H Yaen whose telephone number is 703-
305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone
numbers for the organization where this application or proceeding is assigned are 703-
308-4242 for regular communications and 703-305-3014 for After Final
communications.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is 703-308-
0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
July 24, 2003